

REMARKS

The present invention relates in part to assay devices for the detection of an analyte of interest. These devices comprise a housing; a first device region for receiving a fluid sample; and a second device region fluidly connected to said first device region and comprising one or more capture zones on a surface within said housing. Each capture zone comprises molecules of a first antibody or binding fragment thereof reactive with an analyte of interest and at least one analyte sensor configured and arranged to detect an electrochemical signal related to reaction of a detectable amount of the analyte of interest with the first antibody. The devices also comprise a labeled reagent species dissolvably disposed on a surface within the housing that is in fluid communication with the second device region. This labeled reagent species comprises an enzyme conjugated to a second antibody or binding fragment thereof reactive with the analyte of interest, and form sandwich complexes with the analyte of interest and with the first antibody.

By this submission, claims 1-10 and 18-24, which have been withdrawn from consideration by the Examiner following restriction and election, are cancelled.

Applicant requests reconsideration of the claims in view of the foregoing amendments and the following remarks.

1. 35 U.S.C. §112, second paragraph

Applicant respectfully submits that the Examiner is incorrect that claims 12-17 are indefinite in reciting “A method according to claim ‘x.’” The language to which the Examiner objects indicates that the claim refers back to, and further limits, claim x, in accordance with 37 C.F.R. § 1.75. Applicants note that MPEP 608.01(n) specifically describes the use of the indefinite article in the context of multiple dependent claims. There is nothing of record to indicate that the skilled artisan would understand such language in the context of multiple dependent claims, but somehow would not reasonably understand the very same language in a singular dependent claim.

Moreover, a search of the USPTO issued patent database using the Delphion search system identified 113,873 patents with claims that contain exactly this language. The language requested by the Examiner was found in 139,153 patents. These accuracy of these numbers is

shown by a combination search (“method according to claim”) which identified 242,930 patents. This evidence shows that Applicant’s use of the definite article in the manner at issue is commonly accepted by the USPTO.

In view of the foregoing, Applicant respectfully submits that the claims are not indefinite within the meaning of 35 U.S.C. §112, second paragraph, and requests that the rejection be reconsidered and withdrawn.

2. 35 U.S.C. §102

Applicant respectfully traverses the rejection of claims 11-17 as allegedly being anticipated by U.S. Patent 5,830,680 issued to Meyerhoff *et al.*, as the ‘680 patent is not prior art to the present claims.

As an initial matter, Applicant notes that the rejection refers to Meyerhoff *et al.* as U.S. Patent 5,830,860, rather than 5,830,680, and requests correction should the rejection be maintained.

The earliest filing date for the ‘680 patent is April 26, 1994. This is nearly two years after the earliest priority date of the present application. The earliest application to which the present application claims priority is U.S. patent application Ser. No. 07/887,526, issued as U.S. Pat. No. 5,458,852, which was filed on May 21, 1992.

For the convenience of the Examiner, the following chart provides a listing of where exemplary support for each element of the present claims may be found in the ‘852 patent. This listing is not meant to be limiting, and additional support for various elements of the claims may be found throughout the various priority documents.

11. An assay device comprising:

a housing;

Col. 5, lines 3-6

a first device region formed by or within said housing for receiving a fluid sample; and

Col. 5, lines 47-52

a second device region fluidly connected to said first device region, said second device region comprising one or more capture zones on a surface within said housing, each said capture zone comprising molecules of a first receptor reactive with an analyte of interest and at least one analyte sensor configured and arranged to detect an electrochemical signal related to reaction of a detectable amount of said analyte with molecules of said first receptor and produce a measurable signal in response;

Col. 10, lines 24-27; col. Col 10, lines 10-16

Col. 11, lines 24-29
Col. 3, lines 54-60

a labeled reagent species dissolvably disposed on a surface within said housing that is in fluid communication with said second device region, wherein molecules of said labeled reagent species comprise an enzyme conjugated to a second antibody or binding fragment thereof reactive with said analyte of interest, wherein molecules of said labeled reagent species form sandwich complexes with molecules of said analyte of interest and with molecules of said first antibody or binding fragment thereof.

Col. 3, lines 15-16 and lines 17-25; Col. 6, line 65 – Col. 7, line 2; Col. 10, lines 16-18; Col. 14, lines 39-55.

12. An assay device according to claim 11, wherein said first antibody or binding fragment thereof is bound to one or more latex particles, and said particles are bound to said capture zone.

Col. 10, lines 39-43

13. An assay device according to claim 11, comprising a plurality of capture zones corresponding to a plurality of different analytes of interest.

Col. 10, lines 19-21.

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| 14. An assay device according to claim 11, wherein a predetermined volume of said fluid sample is delivered from said first device region to said second device region by capillary action. | Col. 6, lines 9-17 |
| 15. An assay device according to claim 11, wherein said analyte sensor uses amperometric measurements to detect said electrochemical signal. | Col. 3, line 59 |
| 16. An assay device according to claim 11, wherein said analyte sensor uses potentiometric measurements to detect said electrochemical signal. | Col. 3, line 58 |
| 17. An assay device according to claim 11, wherein said surface within said housing comprising capture zones is an inner surface of the housing. | Col. 12, lines 31-51 |

As Applicant noted in a preliminary amendment filed in this application, U.S. Patent Application No. 08/902,775, issued as U.S. Patent 6,271,040, claims similar subject matter to that claimed herein, in that the '040 patent also relates to assay devices that provide for measurement of at least one analyte of interest through the use of biosensors, and methods for their use. This information is provided solely for the convenience of the Examiner, and is not an admission that the present claims should be considered as variants of the claims issued in the '040 patent.

Because the '680 patent is not prior art to the present claims, Applicant respectfully requests that the rejection be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Respectfully submitted,

Date 07/17/2007

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